



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

FDA Substance Registration System (SRS)

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Why SRS?

- To unambiguously define all substances present in regulated products
- To, within reason, apply definitions in a self-consistent manner.
- To assign a strong non-proprietary identifier (a UNII) that is permanently associated with the defined substance.



What are Substances?

- Any matter (has mass and occupies space) that has discrete existence (Aristotelian view)
 - Well-defined chemical entities
 - Synthetic or naturally-occurring mixtures (isolated together)
 - Structurally-diverse homogeneous natural raw materials
- Single chemical entities
 - Small molecules (graphical structure)
 - Inorganics (chemical formula – includes non-stoichiometric))
 - Proteins (amino acid sequence and modifications)
 - Nucleic acids (nucleotide sequence and modifications)
- Mixtures
 - Groups of related chemical entities - polydisperse natural and synthetic polymers
 - Structurally-diverse materials (defined by their natural (living or non-living) source)



Which Ingredients are Substances?

- Materials that are combined from multiple sources to form a product are not considered substances.
 - Formulations
 - Intermediate product bulk materials
 - Compounded preparations
- Definable modifications to raw materials are substances
Modifications must change the underlying chemical structure or mixture composition (fractionation)
 - Hydrogenation
 - Essential oil
 - Expressed oil
 - Antigen inactivation (e.g. formaldehyde)
- Extracts not definable chemically are associated with the UNII of the source material



How are Substance Definitions Developed?

- What is it?
 - The more information the better
 - We are often given a name only
- Is it new to SRS?
 - If so, a new UNII will be generated
 - If not, it will be connected to an existing UNII
- SRS is a vocabulary where each concept has a code rather than each term
- DSC Vocabulary Standards Working Group
 - Capt. (retired) William Hess



How are Substance Definitions Developed?

- SRS Staff (all chemists)
 - Larry Callahan, Ph.D. J.D.
 - Frank Switzer, Ph.D.
 - Yulia Borodina, Ph.D.
- SRS Review Board
 - All FDA centers represented
 - USP
 - NLM
 - NCI
- Subject matter experts in FDA centers



SRS Preferred Substance Names

- Established Name (Authority Source)
 - US Pharmacopeia (USP)
 - FDA Review Divisions
 - US Adopted Name (USAN/USP Dictionary)
 - International Normalized Name (INN, INNМ)
 - Homeopathic Pharmacopeia US (HPUS)
 - Food Chemicals Codex
 - Herbs of Commerce (SCN)
 - Code of Federal Regulations (GRAS)
 - Personal Care Products Council (INCI)
 - Catalogue of Life (Accepted organism taxons)
 - ITIS (FDA Seafood List)
 - Merck Index
 - Martindale



SRS Preferred Substance Names

➤ Primary Name

When no established name is available

- Code
- Chemical name
- Brand name

➤ Parenthesis

- When an established name is incompletely defined (ambiguous)
- SRS currently requires that each name be unique in the system



SRS Synonyms

- Compiled from authoritative and other public sources
- Appropriately applied names
- May not always be substances themselves
 - Saline vs salt (sodium chloride)
- Have not included brand names associated with active ingredients
 - Actually product names (Advil vs Ibuprofen)
 - SRS board recently agreed to include common brand names from public sources (USAN and Orange Book) to assist in UNII searches



When is an INN or USAN not an SRS Preferred Substance Name?

- When it is a formulation (e.g. Simethicone)
- When it is defined too narrowly (e.g. Botulinum Toxin A's and Erythropoietin's)



When are Different Substance Names Allowed in SPL?

- When different names are required in different domains
TPY09G7XIR
 - Active ingredient - drug - FLUORESCCEIN
 - Inactive ingredient - D&C YELLOW NO. 7
- Listing names may be different from label names



Active Moieties

- Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex chelate or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance.
- § 21CFR25.5(b)(2)
- § 21CFR316.3(b)(2)
- § 21CFR314.108(a)



Amoxicillin (USP)

C₁₆H₁₉N₃O₅S·3H₂O 419.45

AMOXICILLIN UNII-804826J2HU

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino-3,3-dimethyl-7-oxo-, trihydrate 2S-[2,[5,6(S*)]]-.

(2S,5R,6R)-6-[(R)-()-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate[61336-70-7].

Anhydrous 365.41[26787-78-0].

AMOXICILLIN ANHYDROUS UNII-9EM05410Q9

» Amoxicillin contains not less than 900 µg and not more than 1050 µg of C₁₆H₁₉N₃O₅S per mg, calculated on the anhydrous basis.



Where Can I Find UNII's?

➤ Weekly Updates

- FDA – Spreadsheet (currently Excel 2003)
 - <http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm>
- NLM – Name and UNII Search
 - <http://fdasis.nlm.nih.gov/srs/srs.jsp>

➤ Occasional Updates

- USP Dictionary
- Martindale (coming soon)
- Merck (coming soon)



<http://fdasis.nlm.nih.gov/srs/srs.jsp>

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National Library of Medicine
National Institutes of Health

Substance Registration System - Unique Ingredient Identifier (UNII)

Search

Substance Registration System

Information available for 16,748 substances.

☒ By Name ☐ By UNII

► Show examples.

► Show UNII information and download list.

► Substance Registration System FAQ's.

► About Substance Registration System.

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Name Search with Suggestions

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National Library of Medicine
National Institutes of Health

Substance Registration System - Unique Ingredient Identifier (UNII)

Search

Substance Registration System

Information available for 14,284 drugs.

☒ By Name ☐ By UNII

diaz

▶ **S**

DIAZENEDICARBOXAMIDE

DIAZEPAM

DIAZEPAM INTENSOL

DIAZINON

DIAZOLIDINYLUREA

DIAZOXIDE

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Search Output

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National Institutes of Health

Substance Registration System - Unique Ingredient Identifier (UNII)

Home > Search Results

Search
Substance Registration System

☒ By Name ☐ By UNII

[Go back to previous page.](#)

Search Results
Substance Name: DIAZEPAM [\[show more names\]](#)
UNII: UNII-Q3JTX2Q7TU

Resources
[ChemIDplus](#)
[DrugPortal](#)
[Go back to previous page.](#)

Information - Windows Internet Expl...
about:blank

Synonyms
DIAZEPIN
LA-III
METHYL DIAZEPINONE
NSC 77518
NSC-77518
Q3JTX2Q7TU
RO 5-2807
RO-5-2807
UNII-Q3JTX2Q7TU
WY-3467

Internet 100%

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NLM ChemIDPlus Link

The screenshot displays the NLM ChemIDPlus Advanced web interface. The top navigation bar includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health" on the left, and the NLM logo with "United States National Library of Medicine National Institutes of Health" on the right. Below this, the page is titled "Substance Registration System - Unique Ingredient Identifier (UNII)".

On the left side, there is a "Search" box with the text "Substance Registration System" and a "Go" button. Below the search box, there are links to "Go back to previous page." and "Search Results". The "Search Results" section shows the "Substance Name: DIAZEPAM" and "UNII: UNII-Q3JTX2Q7TU". Below this, there is a "Resources" section with links to "ChemIDplus" and "DrugPortal". At the bottom of the left sidebar, there is a "Go back to previous page." link and a footer with site map, contact, and copyright information.

The main content area shows the "ChemIDplus Advanced" header with the NLM logo. Below the header, there is a "NAME: Diazepam [USAN:INN:BAN:JAN]" and "RN: 439-14-5". To the right of the text is a chemical structure diagram of Diazepam. Below the structure, the molecular weight "MW: 284.7447" is displayed, along with a link to "Enlarge Structure".

At the bottom of the main content area, there is a "Basic Information" section with a "Full Record" link. To the right of this is a "Search Navigation" section with a "Start New Query" link. Below the "Basic Information" section is a "File Locator" section with a text box and a "Go" button.



NLM Drug Portal Link

The screenshot displays the NLM Drug Portal interface. At the top, the FDA logo and 'U.S. Food and Drug Administration' are on the left, and the NLM logo and 'United States National Library of Medicine' are on the right. The main header reads 'Substance Registration System - Unique Ingredient Identifier (UNII)'. Below this, a search bar is visible with 'DIAZEPAM' entered and a 'Go' button. The search results section shows 'Substance Name: DIAZEPAM' and 'UNII: UNII-Q3JTX2Q7TU'. A 'Resources' sidebar on the left lists 'ChemIDplus' and 'DrugPortal'. The main content area shows a detailed description of Diazepam, including its classification as a benzodiazepine and its uses in treating anxiety disorders and insomnia. A 'Summary' section at the bottom provides links to various drug information resources like MedlinePlusDrug, LactMed, and ClinicalTrials.gov.

Search Results

Substance Name: DIAZEPAM [show more names]
UNII: UNII-Q3JTX2Q7TU

Resources

- ChemIDplus
- DrugPortal

Search Results

Drug Name: Diazepam [USAN:INN:BAN:JAN] [show more names]
Search Term: UNII-Q3JTX2Q7TU
Description: A benzodiazepine with anticonvulsant, anxiolytic, sedative, muscle relaxant, amnesic properties and a long duration of action. Its actions are mediated by enhancement of GAMMA-AMINOBUTYRIC ACID activity. It is used in the treatment of severe anxiety disorders, as a hypnotic in the short-term management of insomnia, as a sedative and premedicant, as an anticonvulsant, and in the management of alcohol withdrawal syndrome. (From Martindale, The Extra Pharmacopoeia, 30th ed, p589).
Categories: Adjuvants, anesthesia [show more categories]

Summary

- Summary of drug information (MedlinePlusDrug)
- Summary of consumer health information (MedlinePlusTopics)
- Summary of the effect on breastfeeding (LactMed)
- Manufacturers drug label (DailyMed)
- Clinical trials (ClinicalTrials.gov)
- Drug Identification and Image Display (Pillbox beta)



UNII Search

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Search

Substance Registration System

Information available for 14,284 drugs.

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CC

CC6X0L40GW

▶

CC9149U2QX

CC995ZMV90

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Embedded Name Search

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Substance Registration System - Unique Ingredient Identifier (UNII)

Home ▶ Search Results

Search
Substance Registration System

☒ By Name ☐ By UNII

Search Results: Substance Name Order Based on PubMed Citation Count

Substance Name Search: [1](#)

- 1,1,1-TRICHLOROETHANE
- 1,2,4-TRICHLOROBENZENE
- 2,2,2-TRICHLOROETHANOL
- 2-CHLORO-4-PHENYLPHENOL
- 3,4-DICHLOROCINNAMIC ACID
- ABARELIX
- ACAPRAZINE
- ACECLOFENAC
- ACEFYLLINE CLOFIBROL
- ACEMETACIN

Results: 1 - 10 of 752 Go to item:

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